

## REMARKS

### I. Amendment

By this amendment, claims 1 and 2 have been amended and claims 3 and 4 have been cancelled.

This amendment adds no new matter to the specification. Support for the amendment to claim 1 may be found at page 23, line 31 – page 24, line 29 *inter alia*.

### II. Discussion of the Objection to the Declaration

The Examiner has objected to the Declaration for allegedly misspelling the name of one of the inventors. However, Applicants do not believe that the Declaration is defective. Apparently when Dr. Namba's name is translated from Japanese to English, both the spellings of Nanba and Namba may be used.

Applicants believe that the rule which applies to this situation is under Sec. 605.04(b) of the MPEP. Therein, it is stated that a new Declaration is not necessary for typographical or transliteration errors in the spelling of an inventor's name. The interchange of the letters "n" and "m" may be considered to be a transliteration of the foreign name, though not an error.

Therefore Applicants respectfully request withdrawal of the objection to the Declaration.

### III. Discussion of the Objection to the Drawings

The Examiner has indicated that the drawings are unacceptable. Accordingly, formal drawings have been prepared by a professional draftsman. The formal drawings accompany this response.

Therefore Applicants respectfully request withdrawal of the objection to the drawings.

#### **IV. Discussion of the Objection to Claims 3 and 4**

Claims 3 and 4 have been objected to for not properly indicating the status of the claims. By this amendment, claims 3 and 4 have been cancelled, and their status has properly been indicated.

Therefore Applicants respectfully request withdrawal of the objection to claims 3 and 4.

#### **V. Discussion of the Rejection under 35 U.S.C. Sec. 112, First Paragraph**

Claims 1- 4 have been rejected under 35 U.S.C. Sec. 112, first paragraph for allegedly failing to comply with the written description requirement.

The Examiner has objected to the phrase “wherein said cell is expressing at least three endogenous cytochrome P450 CYP genes” in claim 1 as allegedly non-compliant with the written description requirement. By this amendment, the phrase has been deleted, rendering the rejection moot.

Moreover, by this amendment Applicants have amended claim 1 to recite the enzymes as CYP1A1, CYP1A2 and CYP3A. Applicants believe that support for this amendment may be found in the Examples section of the specification as originally filed, namely in Example 3. For the Examiner’s convenience, Applicants note that the recited OUMS-29 culture of Example 3 is the same as the deposited material FERM BP-6328. This information is provided in the specification at page 21, lines 11-19. Applicants submit that the aspect of their invention set forth in claim 1 as amended is adequately enabled.

Claim 2 has been amended to reflect the activities tested in Example 2, on pages 22 and 23. Applicants therefore assert that there is adequate support for claim 2 as amended.

By this amendment, claims 3 and 4 have been cancelled.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 112, first paragraph rejection.

## **VI. Discussion of the Rejection under 35 U.S.C. Sec. 112, Second Paragraph**

Claims 1-5 have been rejected under 35 U.S.C. Sec. 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim subject matter which Applicants regard as the invention.

The Examiner has objected to the phrase “wherein said cell is expressing at least three endogenous cytochrome P450 CYP genes” in claim 1 as allegedly indefinite. By this amendment, the phrase has been deleted, rendering the rejection moot.

Claims 3 and 4 have been cancelled, and claims 2 and 5 depend from claim 1. Applicants submit that the more specific dependent claim is also definite.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 112, second paragraph rejection.

## **VII. Discussion of a Previous Provisional Double-Patenting Rejection**

In the Office Action dated June 2, 2003, a provisional double patenting rejection was made in view of U.S. Patent Application Serial No. 10/009,158. Applicants requested that the rejection be held in abeyance.

Applicants would now like to inform the Examiner that U.S. Patent Application Serial No. 10/009,158 has matured into U.S. Patent No. 6,756,229. Applicants respectfully request the Examiner’s consideration of the recently-issued patent.

Moreover, the cited patent recites isolated and transformed cell lines derived from human hepatocarcinoma cells, while the present invention is directed to immortalized hepatocyte cell culture of human normal cell origin as set forth in claim 1 as amended. Since hepatic carcinoma cells and normal hepatocytes are functionally different, Applicants do not believe that there are any double patenting issues.



VIII. Conclusion

Reconsideration of the claims is requested. Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, the Examiner is respectfully requested to call Applicants' attorney at (847) 383-3391.

Respectfully submitted,

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